

FACT SHEET FOR PATIENTS

BD Veritor™ System for Rapid Detection of SARS-CoV-2
BD Updated: December 2, 2021

Coronavirus
Disease 2019
(COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the BD Veritor™ System for Rapid Detection of SARS-CoV-2.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

For the most up to date information on COVID-19 please visit the Health Canada COVID-19 webpage:

<https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19.html>

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: <https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/symptoms.html>

What is the BD Veritor™ System for Rapid Detection of SARS-CoV-2?

The BD Veritor™ System for Rapid Detection of SARS-CoV-2 is a type of test called an antigen test. Antigen tests are

designed to detect proteins from the virus that causes COVID-19 in nasal swabs.

Why was my sample tested?

Your sample was tested because i) your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or other risk factors and you are within the first five days of the onset of symptoms, or ii) you are undergoing serial testing even though you do not have symptoms or other risk factors for COVID-19 infection,

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The rapid results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What does it mean if I have a positive test result? If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

Where can I go for updates and more information? The most up-to-date information on COVID-19 is available through the Health Canada webpage: <https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19.html>. In addition, please also contact your healthcare provider with any questions/concerns.

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What does it mean if I have a negative test result?

A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If your test result is negative, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. The amount of antigen in a sample may decrease the longer you have symptoms of infection. In symptomatic people, specimens collected after you have had symptoms for more than 5 days may be more likely to be negative compared to a molecular assay.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

What is serial testing?

Serial testing is when a single person is tested for COVID-19 more than once using the same test. Because the amount of antigen in your sample may change over time and false results may occur, repeated testing may identify more individuals with COVID-19 infection than testing a single time. By repeating testing, it may be possible to more quickly identify cases of COVID-19 infection and reduce spread of infection. Additional testing with a molecular COVID-19 test may be necessary, depending on your individual risk factors and test results.

What are the differences between antigen tests and other COVID-19 tests?

There are different kinds of diagnostic tests for COVID-19. Molecular tests (PCR are the most common type of molecular test used to detect genetic material from the virus). Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection.

If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation. If you will not have an additional test to determine if you are contagious, the Public Health Agency of Canada (PHAC) currently recommends self-isolation can be discontinued if:

- You have had no fever for at least 24 hours (that in one full day of no fever without the use of medicine that reduces fevers).

AND

- Other symptoms have improved (for 24 hours, 48 hours for gastrointestinal symptoms)

AND

- At least 10 days have passed since your symptoms first appeared.

For up to date guidance on home isolation after you have been exposed to COVID-19, please consult:

<https://www.canada.ca/en/public-health/services/publications/diseases-conditions/coronavirus-disease-covid-19-how-to-self-isolate-home-exposed-no-symptoms.html>

For more information, the PHAC has provided guidelines on how to prevent the spread of COVID-19 if you are sick:

<https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/prevention-risks.html#p>

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Is this test Health Canada approved?

Yes, this test has been authorized for sale in Canada by Health Canada under Interim Order; authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

- This test is only authorized for the duration of the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, unless the authorization is terminated or revoked sooner;
- This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

What are the approved alternatives?

There are no approved alternative antigen tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an Interim Order, by Health Canada can be found by searching the medical device databases here: <https://health-products.canada.ca/mdall-limh/>

A cleared or approved test should be used instead of a test made available under an Interim Order, when appropriate and available. Health Canada has issued Interim Orders for other tests that can be found at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/list.html>

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